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510(k) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent:	AJW Technology Consultants 962 Allegro Lane Apollo Beach, FL 33572 Tanya O'Brien tmobrien@ajwtech.com 813-645-2855 813-677-4787
Submitter of 510(k):	IntriCon Datrix 340 State Place Escondido, CA 92029
Date of Summary:	September 2, 2011
Trade/Proprietary Name:	Sirona
Classification Name:	Electrocardiograph,ambulatory(without analysis)
Product Code:	MWJ
Intended Use:	The IntriCon Sirona is intended for diagnostic evaluation of patients who experience transient symptoms that may suggest cardiac arrhythmia. When event data is recorded, patients transmit the recorded ECG data over the telephone or directly to a host PC for review by a licensed physician.
Device Description:	The IntriCon Sirona is a device for use as either an Event Recorder (ER), with or without Arrhythmia Detection, or Holter Monitor (HM). The device can operate in one of three modes depending on clinician selected options.
Predicate Device:	Braemar Er900 (K071011/K072008), Datrix VX3 (K031074).

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Substantial Equivalence:	Comparison to the predicate devices listed shows nearly identical technical data, same indications for use, same safety standards tested to, and raises no new questions of safety or efficacy.
Non-Clinical And Performance Testing:	Testing to applicable standards: IEC60601-1:1998, 2nd edition, IEC 60601-1-2: 2001, AAMI EC 38-1998. Testing for the performance, functionality, and reliability characteristics of the device followed established test procedures in a quality system.
Conclusion	Comparison to the predicate devices listed shows nearly identical technical data, same indications for use, same safety standards tested to, and raises no new questions of safety or efficacy. Therefore, the IntriCon Datrix Sirona supports a claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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IntriCon Datrix Corporation
c/o Ms. Tanya O'Brien
Clinical Affairs Specialist
AJW Technology Consultants, Inc.
962 Allegro Lane
Pollo Beach, FL 33572

Re: K112601
Trade/Device Name: IntriCon Datrix Sirona Event/Holter Recorder
Regulatory Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph
Regulatory Class: II (two)
Product Code: MWJ
Dated: September 2, 2011
Received: September 7, 2011

Dear Ms. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112601

Indications for Use Statement

510(k) Number (if known):

Device Name: IntriCon Datrix Sirona Event/Holter Recorder

Model: Sirona

Indications for Use: The IntriCon Datrix Sirona is a combination Event Recorder and Holter Recorder that is intended for diagnostic evaluation of patients who experience transient symptoms that may suggest cardiac arrhythmia. In the Event Recorder mode, once event data is recorded, patients transmit the recorded ECG data over the telephone or directly to a host PC for review by a licensed physician. In the Holter Recorder mode, the device is intended for the recording of ECG data collected from ambulatory patients. The data is then reviewed by the physician after downloading and processing by a Holter playback system.

Contraindications:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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